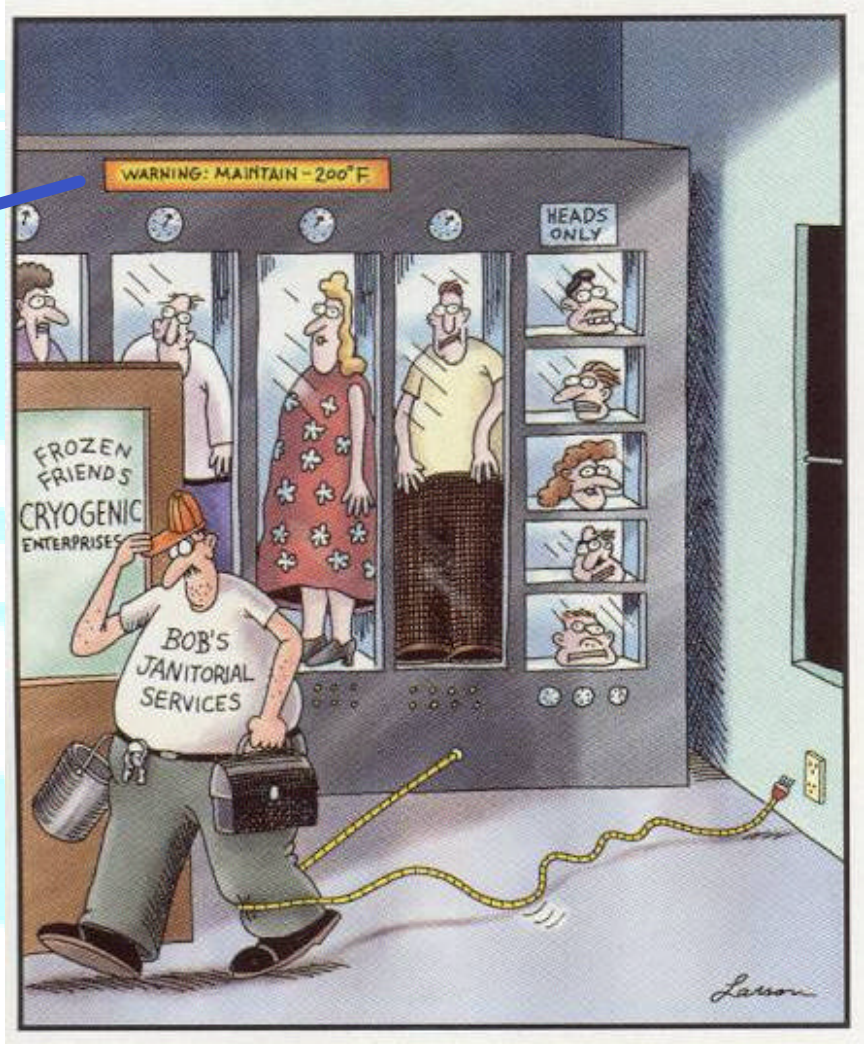
PPTA
Plasma Protein Therapeutics Association

Plasma for Fractionation: A Fractionator's Perspective

FDA's Plasma Standards Workshop
August 31, 2004

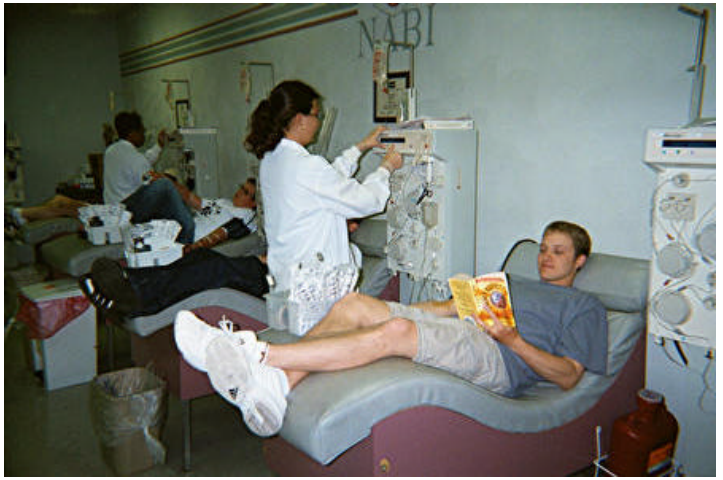
Daniel Albrecht
Sr. Vice President Worldwide Quality, Safety, and Compliance
ZLB Behring (Switzerland)

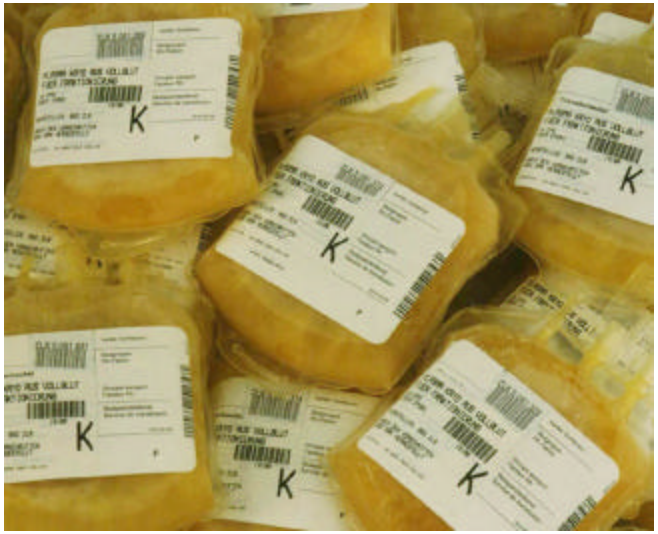
Warning:
Maintain -200°F



Nature of starting material

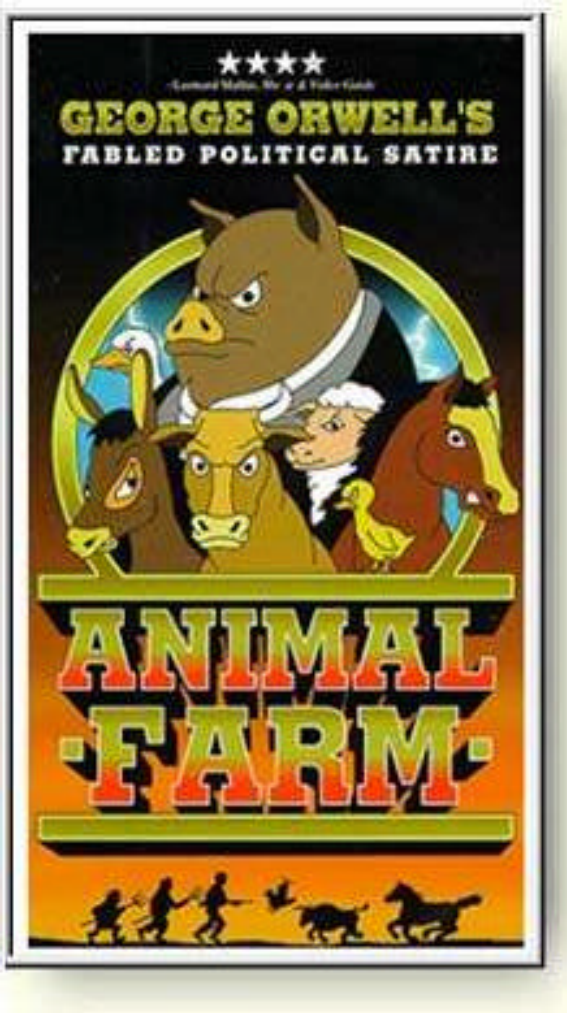
- People For People
- Each unit is unique
- Critical safeguards
  - Screening
  - Robust manufacturing processes
- High costs and ethical responsibility towards donors





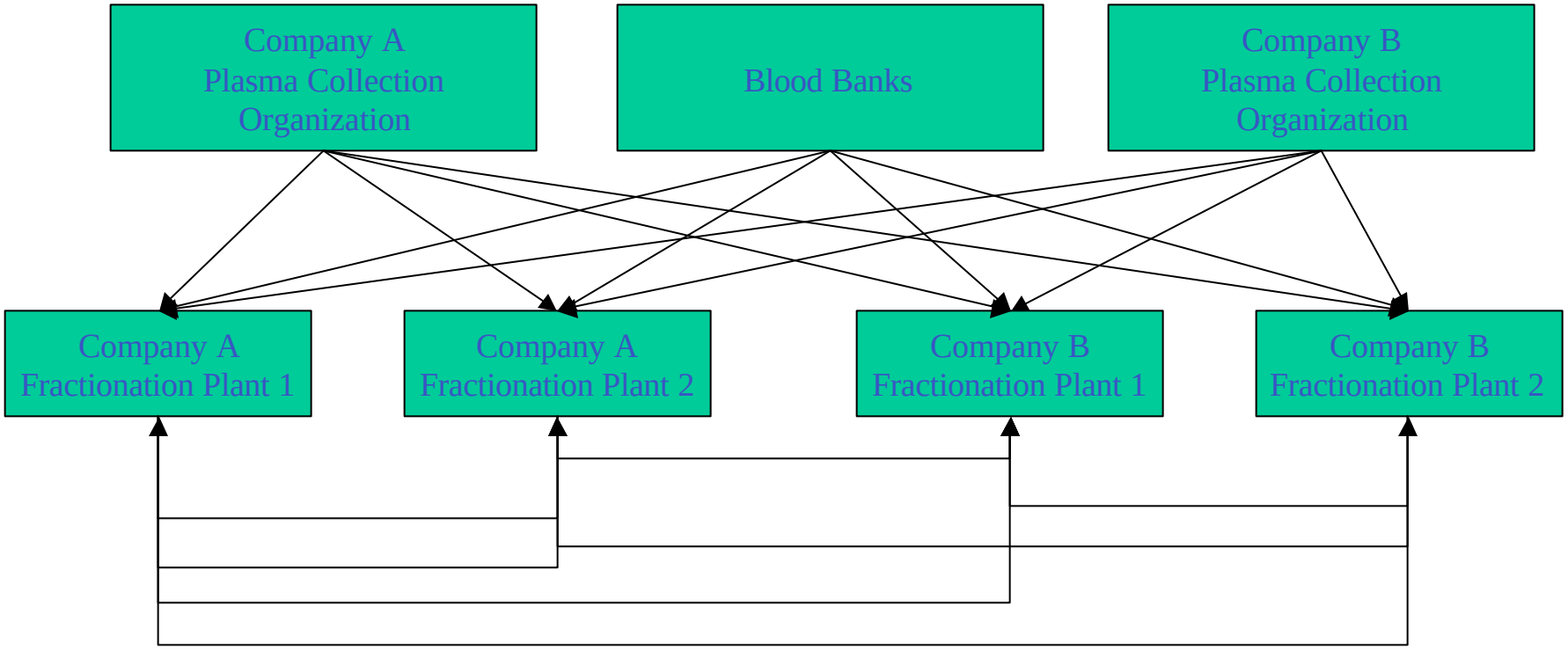
"All plasma is equal"

- Basic Quality measures assure Quality of starting material
- Fractionator's Quality measures maintain, and assure Quality of starting material throughout manufacturing process
- "Perceived" Quality of various plasma sources varies greatly from market to market



Global network of supply

Complex relationships between various parties



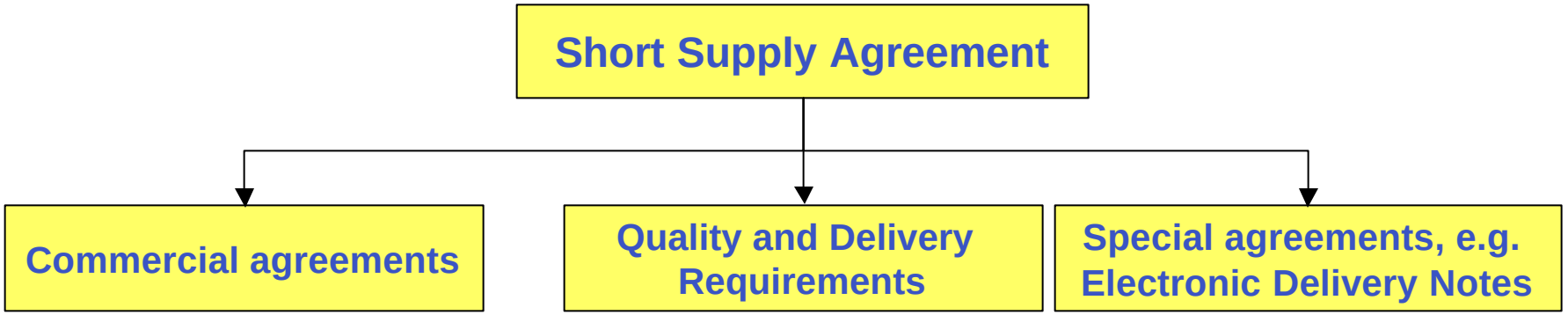
Mature Quality systems

Quality Systems exist to maintain Quality of starting Material and final products

- CFR, Pharmacopoeias
- Council Recommendations (EU), Guidelines
- cGMP's
- Industry standards
- Quality agreements between different parties

Short Supply Agreements

- reference to 21 CFR601.22
- contractual framework document for all additional agreements



Quality and Delivery Requirements

Quality and Delivery Requirements

- General Definitions
- Quality
  - Donor selection and blood donation
  - Collection, processing, storage and transport
  - Plasma specifications
  - Post-collection measures
  - Plasma containers
  - Labeling
- Manufacturing plant
- Compliance and inspection
- Shipping documents
- References

Need for new standards ?

Do we have to develop additional standards for the preparation, labeling, storage and shipping of plasma in order to ensure the safety, purity, and potency of the therapeutically products?

Risk based approach

Pharmaceutical cGMP'S for the 21st Century — A Risk-Based Approach:
Second Progress Report and Implementation Plan

…. To encourage implementation of risk-based approaches that focus both industry and Agency attention on critical areas

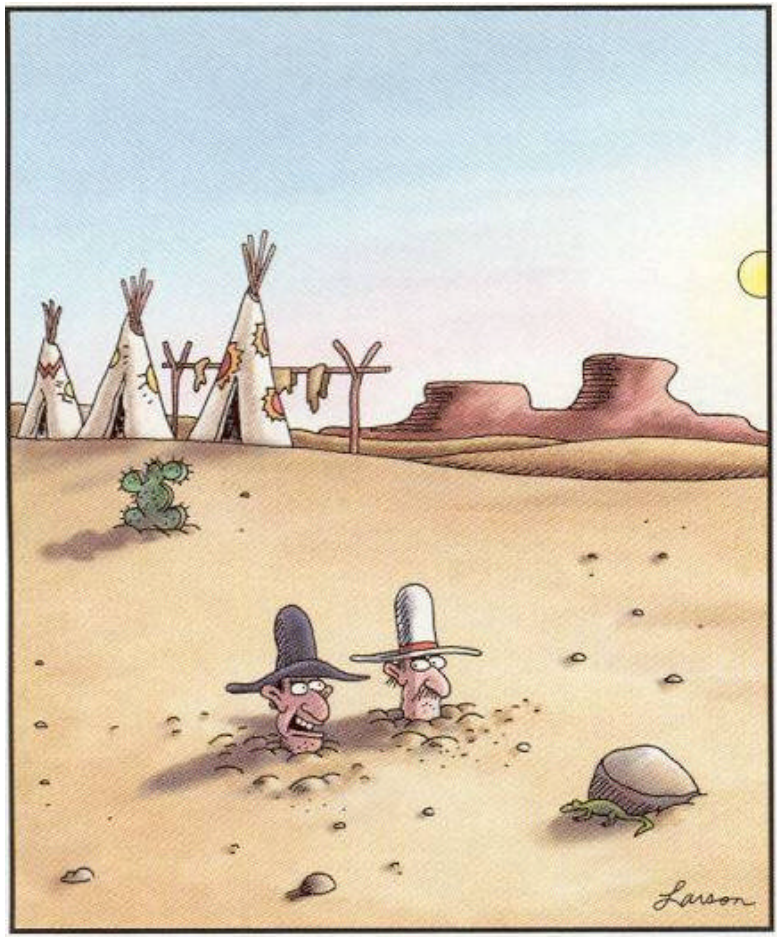
Need for new standards ?

- Basic regulations for freezing/storage/transportation to ensure Quality of final products exist
- Products have been manufactured for decades (> 20 years).
- Immunoglobulin, Albumin
  - Freezing/storage/transport conditions somewhat less significant for Quality of final products
  - Microbiological baseline control has to be taken into consideration

Need for new standards ?

- Factor products
  - Time to freezing should be minimized in order to avoid activation/yield loss
  - Once plasma is frozen, temperature (storage, transport) has minor impact on final product Quality

Need for new standards ?



"Hey, Frank … nice and cool here in the shade … yesiree … niiiiiiice and cool."

Need for new standards ?

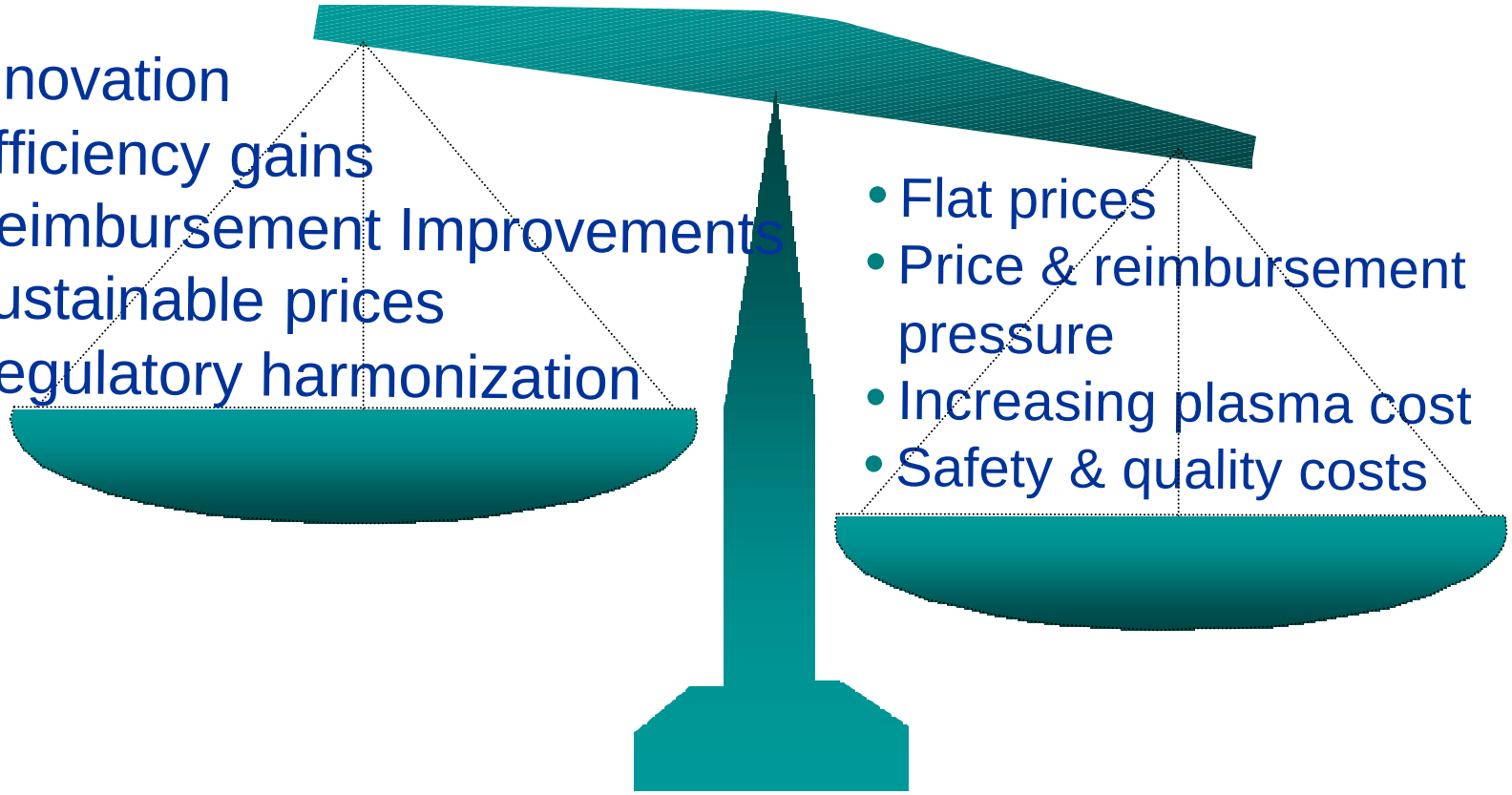
- cGMP's require establishment of clear relationships between different supply parties, this includes (not all inclusive)
  - Establishment of delivery requirement
  - Establishment of specification
  - Audits

- Review of Recalls/Withdrawals published on CBER homepage: No recalls in the last 4 years due to inadequate temperature regulations

Harmonization

- e.g. to allow global utilization of plasma sources
- Harmonization has to be guided by scientific principles
- Regulatory activities should be focused around basic Quality, Safety and Efficacy issues

Economics of Industry



Conclusions

Today's standards are adequate for the preparation, labeling, storage and shipping of plasma to ensure the safety, purity, and potency of the products

Focus both industry and agency attention on more critical areas

Conclusions

"Oh, man! The coffee's *cold*!
They thought of *everything*!"